

**UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE**

GENUS LIFESCIENCES INC.,

Plaintiff,

v.

LANNETT COMPANY, INC.,

Defendant.

C.A. No. 20-cv-770-LPS

JURY TRIAL DEMANDED

LANNETT COMPANY, INC.’S ANSWER TO COMPLAINT AND COUNTERCLAIMS

Defendant Lannett Company, Inc. (“Lannett”) hereby sets forth its Answer and Counterclaims in response to the Complaint of Plaintiff Genus Lifesciences Inc. (“Genus”) as follows:

PRELIMINARY STATEMENT

1. Paragraph 1 states legal conclusions to which no answer is required. To the extent an answer is required, Lannett admits that Genus, through the Complaint, purports to allege infringement of U.S. Patent Nos. 9,867,815 (the “’815 Patent”), 10,016,407 (the “’407 Patent”), and 10,420,760 (the “’760 Patent”) under the patent laws of the United States, Title 35, United States Code § 100 *et seq.* Lannett denies that Lannett has infringed any valid claim of any of the ’815 Patent, ’407 Patent, or ’760 Patent. Lannett otherwise denies the allegations of Paragraph 1.

2. Lannett admits, on information and belief, that Genus is the holder of NDA No. 209963 for a product called “GOPRELTO”, and that the U.S. Federal Food and Drug Administration (“FDA”) approved “GOPRELTO” for the induction of local anesthesia of the mucous membranes when performing diagnostic procedures and surgeries on or through the

nasal cavities in adults in December 2017. Lannett is without sufficient information to form a belief as to the remaining allegations set forth in Paragraph 2, and thus denies them.

3. Paragraph 3 states legal conclusions to which no answer is required. To the extent an answer is required, Lannett states that it is without sufficient information to form a belief as to the remaining allegations set forth in Paragraph 3, and thus denies them.

4. Lannett admits that it manufactures and sells pharmaceutical products in the U.S., including a topical cocaine hydrochloride product under the tradename NUMBRINO®, and that Genus also sells a topical cocaine hydrochloride product called GOPRELTO. Lannett does not know what Genus means by “similar” and therefore denies that GOPRELTO and NUMBRINO are similar, and except as admitted herein, denies the remaining allegations set forth in Paragraph 4.

THE PARTIES, JURISDICTION, AND VENUE

5. Lannett admits the allegations of Paragraph 5 upon information and belief.

6. Lannett admits the allegations of Paragraph 6.

7. Paragraph 7 states legal conclusions to which no answer is required. To the extent an answer is required, Lannett does not contest that this Court has subject matter jurisdiction over this action.

8. Paragraph 8 states legal conclusions to which no answer is required. To the extent an answer is required, Lannett does not contest that venue in this jurisdiction with respect to Genus’s Complaint is proper.

9. Paragraph 9 states legal conclusions to which no answer is required. To the extent an answer is required, Lannett does not contest personal jurisdiction in this judicial district for the limited purpose of this action only.

10. Lannett does not contest personal jurisdiction in this judicial district for the limited purpose of this action only. Lannett denies the remaining allegations of Paragraph 10 as stated.

11. Lannett admits the allegations of Paragraph 11.

THE PATENTS ASSERTED BY GENUS

12. Lannett admits, upon information and belief, that the PTO issued the '815 Patent on January 16, 2018 to Genus as assignee, but denies that the '815 Patent is valid. Lannett is without sufficient information to form a belief as to the remaining allegations set forth in Paragraph 12.

13. Lannett admits that Exhibit A purports to be a copy of the '815 Patent.

14. Paragraph 14 states legal conclusions to which no answer is required. To the extent that an answer is required, Lannett states that the '815 Patent speaks for itself and denies Genus's characterization of the '815 Patent as stated.

15. Lannett admits, upon information and belief, that the PTO issued the '407 Patent on July 10, 2018 to Genus as assignee, but denies that the '815 Patent is valid. Lannett is without sufficient information to form a belief as to the remaining allegations set forth in Paragraph 15 and thus denies them.

16. Lannett admits that Exhibit B purports to be a copy of the '407 Patent.

17. Paragraph 17 states legal conclusions to which no answer is required. To the extent that an answer is required, Lannett states that the '407 Patent speaks for itself and denies Genus's characterization of the '407 Patent as stated.

18. Lannett admits, upon information and belief, that PTO issued the '760 Patent on September 24, 2019 to Genus as assignee, but denies that the Patent is valid. Lannett is without

sufficient information to form a belief as to the remaining allegations set forth in Paragraph 18 and thus denies them.

19. Lannett admits that Exhibit C purports to be a copy of the '760 Patent.

20. Paragraph 20 states legal conclusions to which no answer is required. To the extent that an answer is required, Lannett states that the '760 Patent speaks for itself and denies Genus's characterization of the '760 Patent as stated.

LANNETT'S INFRINGEMENT OF THE PATENTS-IN-SUIT

21. Lannett admits allegations of Paragraph 21.

22. Lannett admits that Cody Labs is a wholly-owned subsidiary of Lannett, that Cody Labs has ceased operations, and that employees of Lannett have received correspondence from the FDA relating to NDA No. 209575. The remaining allegations of Paragraph 22 state legal conclusions to which no answer is required; to the extent an answer is required, Lannett denies those allegations.

23. Lannett admits that it sells NUMBRINO with an insert containing Prescribing Information, which speaks for itself.

24. Lannett admits that Exhibit D is a copy of prescribing information for NUMBRINO.

25. Lannett admits that it sells NUMBRINO in a bottle containing the recited ingredients. Lannett admits that Cody Labs filed the cited patent application, which speaks for itself. Lannett does not know what Genus means by "similar" and therefore denies that the cited measurements are similar, and except as admitted herein, denies the remaining allegations of Paragraph 25.

26. The NUMBRINO label contains a section titled “2.3 Preparation and Administration of NUMBRINO via Pledgets,” which speaks for itself. Lannett denies Genus’s characterizations of the NUMBRINO label as stated.

27. Lannett admits that the NUMBRINO label includes the quoted language and otherwise speaks for itself. Lannett denies Genus’s characterizations of the NUMBRINO label as stated. Lannett admits that nasal endoscopy is a diagnostic procedure or surgery conducted on or through the nasal cavity.

28. Lannett denies the allegations of Paragraph 28.

29. Lannett denies the allegations of Paragraph 29.

COUNT I
(Infringement of the ’815 Patent)

30. Lannett incorporates by reference its responses to Paragraph 1-29 of Genus’s Complaint.

31. Lannett admits the allegations of Paragraph 31.

32. Lannett denies the allegations of Paragraph 32.

33. Lannett admits the allegations of Paragraph 33.

34. To the extent that Paragraph 34 cites to the NUMBRINO label, Lannett states that the NUMBRINO label speaks for itself. Lannett denies the remaining allegations of Paragraph 34.

35. Lannett admits the first sentence of Paragraph 35. To the extent that Paragraph 35 cites to the NUMBRINO label, Lannett states that the NUMBRINO label speaks for itself. Lannett denies the remaining allegations of Paragraph 35.

36. Lannett admits the allegations of Paragraph 36.

37. To the extent that Paragraph 37 cites to the NUMBRINO label, Lannett states that the NUMBRINO label speaks for itself. Lannett denies the remaining allegations of Paragraph 37.

38. Lannett admits the first sentence of Paragraph 38. To the extent that Paragraph 38 cites to the NUMBRINO label, Lannett states that the NUMBRINO label speaks for itself. Lannett denies the remaining allegations of Paragraph 38.

39. Lannett admits the first sentence of Paragraph 39. To the extent that Paragraph 39 cites to the NUMBRINO label, Lannett states that the NUMBRINO label speaks for itself. Lannett denies the remaining allegations of Paragraph 39.

40. Lannett denies the allegations of Paragraph 40.

41. Lannett denies the allegations of Paragraph 41.

42. Lannett denies the allegations of Paragraph 42.

43. Lannett denies the allegations of Paragraph 43.

44. Lannett denies the allegations of Paragraph 44.

45. Lannett denies the allegations of Paragraph 45.

46. Lannett denies the allegations of Paragraph 46.

47. Lannett denies the allegations of Paragraph 47.

COUNT II
(Infringement of the '407 Patent)

48. Lannett incorporates by reference its responses to Paragraph 1-47 of Genus's Complaint.

49. Lannett admits the allegations of Paragraph 49.

50. Lannett denies the allegations of Paragraph 50.

51. Lannett admits the allegations of Paragraph 51.

52. To the extent that Paragraph 52 cites to the NUMBRINO label, Lannett states that the NUMBRINO label speaks for itself. Lannett denies the remaining allegations of Paragraph 52.

53. Lannett admits the first sentence of Paragraph 53. To the extent that Paragraph 53 cites to the NUMBRINO label, Lannett states that the NUMBRINO label speaks for itself. Lannett denies the remaining allegations of Paragraph 53.

54. Lannett admits the first and last sentences of Paragraph 54. To the extent that Paragraph 54 cites to the NUMBRINO label, Lannett states that the NUMBRINO label speaks for itself. Lannett denies the remaining allegations of Paragraph 54.

55. Lannett admits the first sentence of Paragraph 55. To the extent that Paragraph 55 cites to the NUMBRINO label, Lannett states that the NUMBRINO label speaks for itself. Lannett denies the remaining allegations of Paragraph 55.

56. Lannett admits the allegations of Paragraph 56.

57. To the extent that Paragraph 57 cites to the NUMBRINO label, Lannett states that the NUMBRINO label speaks for itself. Lannett denies the remaining allegations of Paragraph 57.

58. Lannett admits the first sentence of Paragraph 58. To the extent that Paragraph 58 cites to the NUMBRINO label, Lannett states that the NUMBRINO label speaks for itself. Lannett denies the remaining allegations of Paragraph 58.

59. Lannett admits the first and last sentences of Paragraph 59. To the extent that Paragraph 59 cites to the NUMBRINO label, Lannett states that the NUMBRINO label speaks for itself. Lannett denies the remaining allegations of Paragraph 59.

60. Lannett admits the first sentence of Paragraph 60. To the extent that Paragraph 60 cites to the NUMBRINO label, Lannett states that the NUMBRINO label speaks for itself.

Lannett denies the remaining allegations of Paragraph 60.

61. Lannett denies the allegations of Paragraph 61.

62. Lannett denies the allegations of Paragraph 62.

63. Lannett denies the allegations of Paragraph 63.

64. Lannett denies the allegations of Paragraph 64.

65. Lannett denies the allegations of Paragraph 65.

66. Lannett denies the allegations of Paragraph 66.

67. Lannett denies the allegations of Paragraph 67.

68. Lannett denies the allegations of Paragraph 68.

COUNT III
(Infringement of the '760 Patent)

69. Lannett incorporates by reference its responses to Paragraph 1-68 of Genus's Complaint.

70. Lannett admits the allegations of Paragraph 70.

71. Lannett denies the allegations of Paragraph 71.

72. Lannett admits the allegations of Paragraph 72.

73. To the extent that Paragraph 73 cites to the NUMBRINO label, Lannett states that the NUMBRINO label speaks for itself. Lannett admits that estimated glomerular filtration rate is a test sometimes used to measure kidney function. Lannett denies the remaining allegations of Paragraph 73.

74. Lannett admits the first sentence of Paragraph 74. To the extent that Paragraph 74 cites to the NUMBRINO label, Lannett states that the NUMBRINO label speaks for itself.

Lannett denies the remaining allegations of Paragraph 74.

75. Lannett admits the first and last sentences of Paragraph 75. To the extent that Paragraph 75 cites to the NUMBRINO label, Lannett states that the NUMBRINO label speaks for itself. Lannett denies the remaining allegations of Paragraph 75.

76. Lannett admits the first sentence of Paragraph 76. Lannett admits that some types of laryngoscopy are performed through the nasal cavities. To the extent that Paragraph 76 cites to the NUMBRINO label, Lannett states that the NUMBRINO label speaks for itself. Lannett denies the remaining allegations of Paragraph 76.

77. Lannett admits the first and last sentences of Paragraph 77. To the extent that Paragraph 77 cites to the NUMBRINO label, Lannett states that the NUMBRINO label speaks for itself. Lannett denies the remaining allegations of Paragraph 77.

78. Lannett admit the first and last sentences of Paragraph 78. To the extent that Paragraph 78 cites to the NUMBRINO label, Lannett states that the NUMBRINO label speaks for itself. Lannett denies the remaining allegations of Paragraph 78.

79. Lannett admits the first and last sentences of Paragraph 79. To the extent that Paragraph 79 cites to the NUMBRINO label, Lannett states that the NUMBRINO label speaks for itself. Lannett denies the remaining allegations of Paragraph 79.

80. Lannett admits the allegations of Paragraph 80.

81. To the extent that Paragraph 81 cites to the NUMBRINO label, Lannett states that the NUMBRINO label speaks for itself. Lannett admits that estimated glomerular filtration rate

is a test sometimes used to measure kidney function. Lannett denies the remaining allegations of Paragraph 81.

82. Lannett admits the first sentence of Paragraph 82. To the extent that Paragraph 82 cites to the NUMBRINO label, Lannett states that the NUMBRINO label speaks for itself. Lannett denies the remaining allegations of Paragraph 82.

83. Lannett admits the first and last sentences of Paragraph 83. To the extent that Paragraph 83 cites to the NUMBRINO label, Lannett states that the NUMBRINO label speaks for itself. Lannett denies the remaining allegations of Paragraph 83.

84. Lannett admits the first and last sentences of Paragraph 84. To the extent that Paragraph 84 cites to the NUMBRINO label, Lannett states that the NUMBRINO label speaks for itself. Lannett denies the remaining allegations of Paragraph 84.

85. Lannett admits the first sentence of Paragraph 85. To the extent that Paragraph 85 cites to the NUMBRINO label, Lannett states that the NUMBRINO label speaks for itself. Lannett denies the remaining allegations of Paragraph 85.

86. Lannett denies the allegations of Paragraph 86.

87. Lannett denies the allegations of Paragraph 87.

88. Lannett denies the allegations of Paragraph 88.

89. Lannett denies the allegations of Paragraph 89.

90. Lannett denies the allegations of Paragraph 90.

91. Lannett denies the allegations of Paragraph 91.

92. Lannett denies the allegations of Paragraph 92.

93. Lannett denies the allegations of Paragraph 93.

PRAYER FOR RELIEF

Lannett denies all remaining allegations not expressly admitted or responded to herein. Lannett further denies that Genus is entitled to the relief requested, or to any relief whatsoever.

AFFIRMATIVE DEFENSES

1. **Failure to state a claim.** Counts I - III fail to state a claim upon which relief can be granted.

2. **Noninfringement.** Lannett has not and does not infringe any valid claim of the '815 Patent, the '407 Patent, or the '760 Patent, literally or by equivalents, directly or indirectly, and has not done so willfully.

3. **Invalidity.** Each claim of the '815 Patent, the '407 Patent, and the '760 Patent is invalid for failure to satisfy one or more of the requirements of 35 U.S.C. §§ 101, 102, 103, and 112.

4. **Estoppel.** Genus is estopped from asserting claims against Lannett for infringement of the '815 Patent, '407 Patent, and '760 Patents. In particular, and among other things:

A. During prosecution of United States Patent No. 10,149,843 ("the '843 Patent"), the applicants stated that the "disclosed and claimed cocaine hydrochloride aqueous solution is different from the Lannett Company's cocaine hydrochloride solution."

B. Similarly, during prosecution of United States Patent Nos. 10,231,961 ("the '961 Patent"), the applicants also stated that the "the cocaine hydrochloride aqueous solution disclosed in the *Subject Application* and recited in the claims is different from the Lannett Company's cocaine hydrochloride solution." Thereafter, in the Notice of Allowance for the '961 Patent, the examiner stated that "Applicants' claims are construed to not encompass the cocaine hydrochloride topical solution marketed by Lannett Company and described in

COCAINE HYDROCHLORIDE Topical Solution CII Product Label (Lannett Company, Inc., 2008).”

C. There is no material difference between the formulations of the cocaine hydrochloride compositions claimed in the ’843 and ’961 Patents and those claimed in Genus’s other Orange Book-listed patents, all of which are from the same patent families as the ’843 and ’961 Patents (including without limitation, the ’815, ’407 and ’760 Patents).

D. Accordingly, these disavowals apply with equal force to the claims of those other Orange Book-listed patents, including the ’815, ’407 and ’760 Patents. And, because NUMBRINO is identical to C-TOPICAL in all material respects, those disavowals also apply with equal force to NUMBRINO.

E. Having been granted patents based on the applicants’ express disavowal of claims covering the Lannett Cocaine Hydrochloride Products, Genus cannot now assert that the manufacture, sale, or use of those Products infringes its patents.

5. **Patent Misuse.** Genus is barred from enforcing the ’815, ’407 and ’760 Patents based on the doctrine of patent misuse because, among other things and without limitation, it has demanded royalties from Lannett for patents that Genus knew or should have known were invalid.

COUNTERCLAIMS

Lannett hereby counterclaims against Genus as follows, and reserves its right to assert additional counterclaims as information becomes available during discovery in this matter.

PARTIES

1. Lannett is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 9000 State Road, Philadelphia, Pennsylvania 19136. Lannett develops, manufactures, and markets pharmaceutical products in the United States.

2. Upon information and belief, Genus is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having a principal place of business at 514 North 12th Street, Allentown, Pennsylvania 18102.

3. Upon information and belief, Genus was previously known as Lehigh Valley Technology, Inc. (“LVT”). On or about May 1, 2017, LVT changed its name to Genus Lifesciences, Inc.

NATURE OF ACTION

4. Lannett seeks declaratory judgment under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.* that the claims of the ’815 Patent, the ’407 Patent, the ’760 Patent, and United States Patent Nos. 10,149,843 (“the ’843 Patent”), 10,231,961 (“the ’961 Patent”), and 10,413,505 (“the ’505 Patent”), (collectively the “Patents in Suit”) are invalid, and have not been infringed, are not being infringed, and will not be infringed by the manufacture, use, sale, offer for sale, or importation of Lannett’s Cocaine Hydrochloride Products.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over these Declaratory Judgment Counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. Genus has filed a Complaint in this District alleging infringement by Lannett of one or more claims of the '815 Patent, '407 Patent, and '760 Patent. In addition, as is described more fully below, Genus has repeatedly asserted that the Patents in Suit cover Lannett's current and past products and has demanded that Lannett pay a royalty on sales of those products, along with the accompanying implicit threat of litigation by Genus against Lannett to enforce those Patents. Therefore, an actual case and controversy exists between Lannett and Genus as to the alleged infringement and validity of each of the Patents in Suit.

7. This Court has personal jurisdiction over Genus because, *inter alia*, Genus has subjected itself to the jurisdiction of this Court by filing its Complaint. In addition, Genus has had continuous and systematic contacts with this judicial district, including conducting business in Delaware and marketing, selling, and distributing pharmaceutical products, including cocaine hydrochloride pharmaceutical products, throughout the United States and in this judicial district.

8. Venue is proper in this District under 28 U.S.C. § 1391 because, *inter alia*, Genus filed its Complaint in this District and has marketed, distributed, and sold pharmaceutical products, including cocaine hydrochloride pharmaceutical products, throughout the United States and in this judicial district.

BACKGROUND

Historical Use and Sale of Cocaine Hydrochloride Products

9. Cocaine hydrochloride, the active ingredient in the Lannett Cocaine Hydrochloride Products (see below), is a topical, local anesthetic and vasoconstrictor commonly

used in connection with many different types of nasal, laryngeal, and oral procedures. Indeed, published literature demonstrates that cocaine hydrochloride products have been used for local anesthesia and vasoconstriction for more than a century. During that time, a variety of manufacturers have sold cocaine hydrochloride formulations in the United States, including Roxane Laboratories, Inc. and Lannett.

10. In 2008, Lannett began selling a cocaine hydrochloride product under the tradename “C-TOPICAL®.” As per its label, C-TOPICAL was used for “the introduction of local (topical) anesthesia of accessible mucous membranes of the oral, laryngeal, and nasal cavities.” Ex. 1. C-TOPICAL acted as both a vasoconstrictor and local anesthetic, and was used by physicians for various types of nasal and other procedures.

Lannett’s NUMBRINO® Product

11. C-TOPICAL was not approved by the FDA, but was marketed subject to the FDA’s enforcement discretion. Consistent with the FDA’s encouragement to manufacturers of unapproved drugs to seek FDA approval for them, on September 21, 2017, Lannett submitted NDA No. 209575, under §505(b)(2) of the Federal Food, Drug, and Cosmetic Act (“FDCA”), seeking FDA approval for its cocaine hydrochloride product, under the tradename “NUMBRINO®.”

12. NUMBRINO is the same product as Lannett’s prior C-TOPICAL product—it is made with the same components, using the same manufacturing process, and is packaged in the same containers as C-TOPICAL was.

13. Lannett sought FDA approval of NUMBRINO based on, among other things, evidence of the safety and efficacy of its C-TOPICAL product and extensive literature

demonstrating the safety and efficacy of cocaine hydrochloride products for use in nasal and other surgeries.

14. In January 2020, the FDA approved Lannett's NDA. As per its label, NUMBRINO is approved for the following indications and usage: "an ester local anesthetic indicated for the introduction of local anesthesia of the mucous membranes for diagnostic procedures and surgeries on or through the nasal cavities of adults." Ex. 2.

15. In approving Lannett's NDA, the FDA relied on, among other things, data reflecting, and gathered during, the long history of the use of cocaine hydrochloride. By way of example only, the FDA opted not to require Lannett to conduct clinical studies on renally-impaired patients, finding that the existing published literature concerning the elimination of cocaine hydrochloride from the body provided sufficient information regarding the treatment of such patients to obviate the need for such studies.

16. Lannett currently sells NUMBRINO® throughout the United States, including in this District. At the FDA's request, Lannett ceased marketing C-TOPICAL in August 2019.¹ C-TOPICAL and NUMBRINO are collectively referred to as the "Lannett Cocaine Hydrochloride Products."

Genus and the Patents in Suit

17. Genus wanted to enter the cocaine hydrochloride market, but had no product of its own. In September 2016, Genus acquired a previously-filed Investigational New Drug ("IND")

¹ As described below, Genus obtained approval for its cocaine hydrochloride product in December 2017, before Lannett's NDA was approved. The FDA's request that Lannett cease selling C-TOPICAL was consistent with the agency's practice of asking manufacturers of unapproved products to withdraw their products from the market at some point after an approved form of the product is available.

Application for a cocaine hydrochloride product named GOPRELTO from Pennsylvania Pain Specialists, P.C. (“PPS”).

18. Shortly thereafter, in November 2016, Genus submitted NDA No. 209963, under §505(b)(2) of the FDCA, seeking FDA approval for PPS’s GOPRELTO product.

19. Genus sought FDA approval of GOPRELTO based on, among other things, the extensive history of the safe and effective use of various cocaine hydrochloride products, including Lannett’s C-TOPICAL, for use in nasal and other surgeries and diagnostic procedures.

20. The FDA approved GOPRELTO in December 2017.

21. GOPRELTO was and is a copy of prior cocaine hydrochloride products, including the Lannett Cocaine Hydrochloride Products. GOPRELTO is comprised of the exact same components as C-TOPICAL and NUMBRINO—namely, an aqueous solution of 4% cocaine hydrochloride, with citric acid, sodium benzoate, D&C Yellow No. 10, FD&C Green No. 3 and purified water.

22. GOPRELTO is approved for use in the same types of nasal procedures, and administered in the same manner for such procedures, as cocaine hydrochloride products have been used and administered for many, many years in connection with those procedures. This includes Lannett’s C-TOPICAL product; Genus’s GOPRELTO product is used and administered in the same way that Lannett’s C-TOPICAL product had been used and administered for nasal surgeries for a decade.

23. Despite the fact that Genus invented nothing, and instead simply copied pre-existing cocaine hydrochloride products such as Lannett’s C-TOPICAL product, Genus sought and obtained patents relating to GOPRELTO that it could list in the FDA’s “Orange Book,” including:

- a. On January 16, 2018, the PTO issued the '815 Patent, entitled "Pharmaceutical Compositions and Methods of Using the Same," to Genus as assignee (a true and correct copy of which is attached as Exhibit 3).
 - b. On July 10, 2018, the PTO issued the '407 Patent, entitled "Pharmaceutical Compositions and Methods of Using the Same," to Genus as assignee (a true and correct copy of which is attached as Exhibit 4).
 - c. On December 11, 2018, the PTO issued the '843 Patent, entitled "Pharmaceutical Compositions and Methods of Using the Same," to Genus as assignee (a true and correct copy of which is attached as Exhibit 5).
 - d. On March 19, 2019, the PTO issued the '961 Patent, entitled "Pharmaceutical Compositions and Methods of Using the Same," to Genus as assignee (a true and correct copy of which is attached as Exhibit 6).
 - e. On September 17, 2019, the PTO issued the '505 Patent, entitled "Pharmaceutical Compositions and Methods of Using the Same," to Genus as assignee (a true and correct copy of which is attached as Exhibit 7).
 - f. On September 24, 2019, the PTO issued the '760 Patent, entitled "Pharmaceutical Compositions and Methods of Using the Same," to Genus as assignee (a true and correct copy of which is attached as Exhibit 8).
24. On information and belief, Genus owns each of the Patents in Suit.
25. Genus submitted information regarding each of the Patents in Suit for listing in the FDA's "Orange Book" with respect to GOPRELTO.

Genus's Patents Are Invalid

26. Genus did not invent anything. It did not conceive of or develop a new or different cocaine hydrochloride product—it simply copied pre-existing products, including Lannett's C-TOPICAL product. Nor did Genus conceive of or develop any new method of using cocaine hydrochloride products—it simply sought FDA approval for using such products in the same manner and for the same indications and procedures that they had been being used for decades, including the same use and manner in which Lannett's C-TOPICAL product was being used.

27. Each of the Patents in Suit is invalid under 35 U.S.C. §§ 102 and/or 103 as anticipated by and/or rendered obvious in view of the public sale and use of various prior art cocaine hydrochloride products, including Lannett's C-TOPICAL product, as well as by extensive prior art publications and patents.

28. The Patents in Suit are also invalid as failing to satisfy one or more of the requirements of 35 U.S.C. §§ 101 and/or 112.

Need for Declaratory Relief

29. Notwithstanding the fact that the Patents in Suit are clearly invalid as set forth above, and the fact that Lannett's C-Topical product was on sale and in public use long before those Patents issued, Genus has repeatedly demanded that Lannett pay a royalty for alleged use of Genus's claimed inventions.

30. In particular, Genus has repeatedly advised Lannett that it believes the Patents in Suit cover Lannett's Cocaine Hydrochloride Products and demanded that Lannett pay a substantial royalty to Genus as compensation for its alleged use of those Patents and the right to continue to practice them. These assertions were intended to and do carry an implicit threat that if Lannett fails to accede to Genus's demands, Genus will seek to enforce the Patents in Suit and to recover those royalties from Lannett via litigation.

31. Those threats have now been realized with respect to the '815,'407 and '760 Patents, by virtue of Genus's filing of its Complaint in this action. Genus filed that Complaint only after Lannett advised Genus that it intended to commence a lawsuit seeking a declaration that the Patents in Suit are invalid and not infringed by the Lannett Cocaine Hydrochloride Products.

32. In addition, Genus has undertaken a variety of other actions in an effort to prevent Lannett from selling its Cocaine Hydrochloride Products. For instance, in February 2019, Genus filed a Citizen's Petition with the FDA seeking to preclude the FDA from further considering or approving Lannett's 505(b)(2) NDA for its NUMBRINO product until after December 2022. That petition was denied. Genus filed a second Citizen Petition in August 2019, requesting (in part) that the FDA rescind its acceptance of Lannett's NUMBRINO NDA. That petition was denied as well. After its Citizen's Petitions failed, in January 2020, Genus filed a lawsuit against the FDA and others seeking, among other things, an order requiring the FDA to rescind its approval of NUMBRINO.

33. Genus has also brought claims to prevent other potential competitors from entering the cocaine hydrochloride market. In November 2019, Genus filed a lawsuit against Mallinckrodt, its supplier of raw cocaine hydrochloride material, seeking to preclude Mallinckrodt from working with other companies who may seek to use Mallinckrodt's raw cocaine hydrochloride material to manufacture and market cocaine hydrochloride products in competition with Genus. *See Genus Lifesciences Inc. v. Mallinckrodt LLC*, No. 19-5403 (E.D. Pa. Nov. 29, 2019), D.I. 5.

34. Genus has also sued Lannett directly, alleging violations of the Lanham Act, Sherman Act, California Business and Professions Code, and common law. *See Genus Lifesciences Inc. v. Lannett Co. et al*, No. 3:18-cv-07603, D.I. 1 (N.D. Cal. Dec. 18, 2018). None of Genus's claims have merit, and many of the claims—including Genus' claims under the Sherman Act—have already been dismissed or withdrawn, but the lawsuit is still pending.

35. In view of Genus's repeated assertions that the Patents in Suit cover Lannett's Hydrochloride Products, repeated demands that Lannett pay a substantial royalty in exchange for

a license to practice those Patents, demonstrated propensity to file lawsuits to protect GOPRELTO against competition from Lannett's Cocaine Hydrochloride Products and other potential competitors, and the filing of the Complaint in this action, there is a definite and concrete controversy between Genus and Lannett as to whether each of the Patents in Suit are valid and whether Lannett's past and future sales of its Cocaine Hydrochloride Products infringe those Patents.

36. Despite Genus's overt and implied threats that it will seek to enforce all of the Patents in Suit against Lannett, and its filing of the Complaint in this action, it is clear that all of the claims of the Patents in Suit are either invalid or not infringed by Lannett's Cocaine Hydrochloride Products.

37. On the one hand, to the extent any claimed invention of the Patents in Suit purportedly covers Lannett's Cocaine Hydrochloride Products, it is anticipated by and/or rendered obvious in view of, among other things, the prior sale and public use of Lannett's C-TOPICAL product for a decade before Genus applied for its patents.

38. On the other hand, to the extent any claimed invention of the Patents in Suit does not cover Lannett's Cocaine Hydrochloride Products, it has not been and will not be infringed by Lannett's past or future sales of those Products.

39. Moreover, Genus is estopped from asserting claims against Lannett for infringement of the Patents in Suit for the reasons set forth above in Lannett's Affirmative Defenses, ¶¶ 4-8. Lannett hereby incorporates by reference the allegations of those paragraphs.

40. Thus, it is necessarily the case that every claim of the Patents in Suit is either invalid or not infringed by Lannett's Cocaine Hydrochloride Products. Accordingly, Lannett is entitled to the declaratory relief sought herein.

COUNT I
INVALIDITY OF THE '815 PATENT

41. Lannett incorporates each of the preceding paragraphs as if fully set forth herein.

42. There is an actual, substantial, and continuing justiciable case or controversy between Lannett and Genus, having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning the invalidity of the '815 Patent.

43. The claims of the '815 Patent are invalid for at least failure comply with one or more conditions for patentability set forth in Title 35 of the United States Code.

44. Lannett is entitled to a declaratory judgment that the claims of the '815 Patent are invalid.

COUNT II
NON-INFRINGEMENT OF THE '815 PATENT

45. Lannett incorporates each of the preceding paragraphs as if fully set forth herein.

46. There is an actual, substantial, and continuing justiciable case or controversy between Lannett and Genus, having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning the non-infringement of the '815 Patent.

47. Lannett has not infringed, is not infringing, and will not infringe, either directly or indirectly, any valid and enforceable claim of the '815 Patent.

48. Moreover, Genus is estopped from asserting that the Lannett's manufacture, sale or use of its Cocaine Hydrochloride Products infringes, either directly or indirectly, the '815 Patent.

49. Lannett is entitled to a declaratory judgment that the making, using, offering to sell, selling, and/or importing of the Lannett Cocaine Hydrochloride Products does not, has not, and will not infringe any valid and enforceable claims of the '815 Patent.

COUNT III
INVALIDITY OF THE '407 PATENT

50. Lannett incorporates each of the preceding paragraphs as if fully set forth herein.

51. There is an actual, substantial, and continuing justiciable case or controversy between Lannett and Genus, having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning the invalidity of the '407 Patent.

52. The claims of the '407 Patent are invalid for at least failure comply with one or more conditions for patentability set forth in Title 35 of the United States Code.

53. Lannett is entitled to a declaratory judgment that the claims of the '407 Patent are invalid

COUNT IV
NON-INFRINGEMENT OF THE '407 PATENT

54. Lannett incorporates each of the preceding paragraphs as if fully set forth herein.

55. There is an actual, substantial, and continuing justiciable case or controversy between Lannett and Genus, having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning the non-infringement of the '407 Patent.

56. Lannett has not infringed, is not infringing, and will not infringe, either directly or indirectly, any valid and enforceable claim of the '407 Patent.

57. Moreover, Genus is estopped from asserting that the Lannett's manufacture, sale or use of its Cocaine Hydrochloride Products infringes, either directly or indirectly, the '407 Patent.

58. Lannett is entitled to a declaratory judgment that the making, using, offering to sell, selling, and/or importing of the Lannett Cocaine Hydrochloride Products does not, has not, and will not infringe any valid and enforceable claims of the '407 Patent

COUNT V
INVALIDITY OF THE '843 PATENT

59. Lannett incorporates each of the preceding paragraphs as if fully set forth herein.

60. There is an actual, substantial, and continuing justiciable case or controversy between Lannett and Genus, having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning the invalidity of the '843 Patent.

61. The claims of the '843 Patent are invalid for at least failure comply with one or more conditions for patentability set forth in Title 35 of the United States Code.

62. Lannett is entitled to a declaratory judgment that the claims of the '843 Patent are invalid.

COUNT VI
NON-INFRINGEMENT OF THE '843 PATENT

63. Lannett incorporates each of the preceding paragraphs as if fully set forth herein.

64. There is an actual, substantial, and continuing justiciable case or controversy between Lannett and Genus, having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning the non-infringement of the '843 Patent.

65. Lannett has not infringed, is not infringing, and will not infringe, either directly or indirectly, any valid and enforceable claim of the '843 Patent.

66. Moreover, Genus is estopped from asserting that the Lannett's manufacture, sale or use of its Cocaine Hydrochloride Products infringes, either directly or indirectly, the '843 Patent.

67. Lannett is entitled to a declaratory judgment that the making, using, offering to sell, selling, and/or importing of the Lannett Cocaine Hydrochloride Products does not, has not, and will not infringe any valid and enforceable claims of the '843 Patent

COUNT VII
INVALIDITY OF THE '961 PATENT

68. Lannett incorporates each of the preceding paragraphs as if fully set forth herein.

69. There is an actual, substantial, and continuing justiciable case or controversy between Lannett and Genus, having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning the invalidity of the '961 Patent.

70. The claims of the '961 Patent are invalid for at least failure comply with one or more conditions for patentability set forth in Title 35 of the United States Code.

71. Lannett is entitled to a declaratory judgment that the claims of the '961 Patent are invalid.

COUNT VIII
NON-INFRINGEMENT OF THE '961 PATENT

72. Lannett incorporates each of the preceding paragraphs as if fully set forth herein.

73. There is an actual, substantial, and continuing justiciable case or controversy between Lannett and Genus, having adverse legal interests of sufficient immediacy and reality to

warrant the issuance of a declaratory judgment concerning the non-infringement of the '961 Patent.

74. Lannett has not infringed, is not infringing, and will not infringe, either directly or indirectly, any valid and enforceable claim of the '961 Patent.

75. Moreover, Genus is estopped from asserting that the Lannett's manufacture, sale or use of its Cocaine Hydrochloride Products infringes, either directly or indirectly, the '961 Patent.

76. Lannett is entitled to a declaratory judgment that the making, using, offering to sell, selling, and/or importing of the Lannett Cocaine Hydrochloride Products does not, has not, and will not infringe any valid and enforceable claims of the '961 Patent.

COUNT IX
INVALIDITY OF THE '505 PATENT

77. Lannett incorporates each of the preceding paragraphs as if fully set forth herein.

78. There is an actual, substantial, and continuing justiciable case or controversy between Lannett and Genus, having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning the invalidity of the '505 Patent.

79. The claims of the '505 Patent are invalid for at least failure comply with one or more conditions for patentability set forth in Title 35 of the United States Code.

80. Lannett is entitled to a declaratory judgment that the claims of the '505 Patent are invalid.

COUNT X
NON-INFRINGEMENT OF THE '505 PATENT

81. Lannett incorporates each of the preceding paragraphs as if fully set forth herein.

82. There is an actual, substantial, and continuing justiciable case or controversy between Lannett and Genus, having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning the non-infringement of the '505 Patent.

83. Lannett has not infringed, is not infringing, and will not infringe, either directly or indirectly, any valid and enforceable claim of the '505 Patent.

84. Moreover, Genus is estopped from asserting that the Lannett's manufacture, sale or use of its Cocaine Hydrochloride Products infringes, either directly or indirectly, the '505 Patent.

85. Lannett is entitled to a declaratory judgment that the making, using, offering to sell, selling, and/or importing of the Lannett Cocaine Hydrochloride Products does not, has not, and will not infringe any valid and enforceable claims of the '505 Patent.

COUNT XI
INVALIDITY OF THE '760 PATENT

86. Lannett incorporates each of the preceding paragraphs as if fully set forth herein.

87. There is an actual, substantial, and continuing justiciable case or controversy between Lannett and Genus, having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning the invalidity of the '760 Patent.

88. The claims of the '760 Patent are invalid for at least failure comply with one or more conditions for patentability set forth in Title 35 of the United States Code.

89. Lannett is entitled to a declaratory judgment that the claims of the '760 Patent are invalid.

COUNT XII
NON-INFRINGEMENT OF THE '760 PATENT

90. Lannett incorporates each of the preceding paragraphs as if fully set forth herein.

91. There is an actual, substantial, and continuing justiciable case or controversy between Lannett and Genus, having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment concerning the non-infringement of the '760 Patent.

92. Lannett has not infringed, is not infringing, and will not infringe, either directly or indirectly, any valid and enforceable claim of the '760 Patent.

93. Moreover, Genus is estopped from asserting that the Lannett's manufacture, sale or use of its Cocaine Hydrochloride Products infringes, either directly or indirectly, the '760 Patent.

94. Lannett is entitled to a declaratory judgment that the making, using, offering to sell, selling, and/or importing of the Lannett Cocaine Hydrochloride Products does not, has not, and will not infringe any valid and enforceable claims of the '760 Patent.

PRAYER FOR RELIEF

WHEREFORE, Lannett respectfully requests that this Court grant the following relief:

- A. A judgment that the '815 Patent is invalid;
- B. A judgment that Lannett has not infringed, is not infringing, and will not infringe any valid claim of the '815 Patent;
- C. A judgment that the '407 Patent is invalid;
- D. A judgment that Lannett has not infringed, is not infringing, and will not infringe any valid claim of the '407 Patent;
- E. A judgment that the '843 Patent is invalid;
- F. A judgment that Lannett has not infringed, is not infringing, and will not infringe any valid claim of the '843 Patent;

- G. A judgment that the '961 Patent is invalid;
- H. A judgment that Lannett has not infringed, is not infringing, and will not infringe any valid claim of the '961 Patent;
- I. A judgment that the '505 Patent is invalid;
- J. A judgment that Lannett has not infringed, is not infringing, and will not infringe any valid claim of the '505 Patent;
- K. A judgment that the '760 Patent is invalid;
- L. A judgment that Lannett has not infringed, is not infringing, and will not infringe any valid claim of the '760 Patent;
- M. A judgment that this is an exceptional case pursuant to Section 285 of Title 35 of the United States Code;
- N. Reasonable attorneys' fees, filing fees, and reasonable costs of suit incurred by Lannett in this action; and
- O. Such other and further relief as the Court may deem just and proper.

JURY DEMAND

Lannett hereby demands a jury with respect to all issues so triable.

Dated: June 19, 2020

Respectfully submitted,

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